



SPLaT_ER

SYMPTOM PATTERNS AND LIFE WITH LONGER TERM COVID-19 IN CHILDREN AND YOUNG PEOPLE An Electronic healthcare Records review of long COVID coding in primary care compared with long COVID identified by questionnaire.

ONLINE INFORMATION SHEET

Thank you for reading this information sheet which has been written with children and young people in mind. If you are a parent or guardian, please read it too, and support your child with it if they are younger or don't fully understand what it says. Before you decide if you (or your child) would like to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and talk about it with others if you want to. If anything is not clear to you, if you require this information in a different language or if you would like more information, then please feel free to contact the SPLaT_ER study team on 01782 731273 or at research.splat_er@keele.ac.uk .

There is a version of this leaflet for younger children, available from the home screen

What is this research for?

This research is about Long COVID and COVID-19 in children. 'Long COVID' is an illness in which symptoms of COVID-19 infection last at least 4 weeks, such as tiredness, feeling short of breath and having pain.

There is already an existing Long COVID study called SPLaT-19_C which asks children (or their parents/ carers) if they had COVID-19 and whether they had any long-lasting symptoms (that you have already kindly taken part in). SPLaT_ER is a new study based on the children and young people that took part in SPLaT-19_C. We are only contacting children and young people from SPLaT-19_C that said that it was ok for us to contact them about new studies.

We know that long covid (problems after COVID-19 that continue for more than four weeks) is common in adults but less is known about this in children. We also know that many more people in the UK report having long-covid than is recorded in their general practice health records. We suspect that this is also true for children, but we want to find out for sure. We think that COVID-19 will be better recorded, but again we want to find out for sure.

This new study will ask for permission to link the existing SPLaT-19_C study with general practice health records to see if COVID-19 and long covid are being recorded in children's/young peoples' general practice records and to compare this to the information we have from the answers from questionnaires in the existing study.

It is important to know how well medical records agree with what patients tell us has happened, as anonymised medical records are often used in research to describe how many people are affected by medical conditions and to what extent. We need to know how well medical records agree with what children and young people have told us in the questionnaire about symptoms following COVID-19, as this will help us understand long COVID in children better and help design services to support them.

Who are we and what will we do?

We are a group of doctors and researchers that want to answer questions like:

- Is Long COVID and COVID-19 being recorded in the GP records of children?
- Does COVID-19 and long COVID reported by children match up with their GP records?

We want to answer these questions by looking at the responses children have given us in questionnaires and comparing these to the GP healthcare records. GPs and other healthcare professionals (eg nurses) record lots of different things in healthcare records by using a healthcare code. It is these codes that we want to look for.

How long will the research take?

We are planning to take 6 months to run this study and then around two to three months afterwards to write up our findings and tell people about them including children in child-friendly ways.

Why have I been chosen to help with your research?

We are inviting all children and young people who previously took part in the SPLaT-19_C study (and said that they were happy to be contacted again) to take part in this new study. (These are children who have been registered with GP surgeries in Staffordshire, Shropshire, and the West Midlands.) We want to include people in this age group whether or not they have had COVID-19.

Just to clarify **this new study is NOT trying to ‘check-up’ on your questionnaire responses and will not ‘undo’ any of the previous results.**

We know for lots of symptoms and diseases there is a difference between what patients tell researchers and what their GP practice has recorded for lots of different reasons and investigating these differences is an important part of research.

What will we have to do if we take part?

If you agree to take part, you will be asked if it is OK to contact your GP surgery to find healthcare codes contained in your GP healthcare records associated with both long COVID and COVID-19, including any positive test result codes for COVID-19. We will also ask for the start dates on these codes. We will not ask for any other data in your records. All you will need to do is sign an electronic consent form with enough details to allow us to contact your GP and to be able to identify your healthcare records at the GP practice (using your date of birth and NHS number) and we will not need you to do anything else. As part of identifying your records, a code will be added to your healthcare record indicating that you have agreed to take part in this research study.

Do I have to take part?

No, you do not have to take part.

What will happen if I don't want to carry on with the study?

Even if you say yes to being part of the study now, you can change your mind at any time. The healthcare you receive will not be affected in any way.

What will happen if I am not able to carry on with the study?

If at any time you become unable to give consent to take part in the study, we will withdraw you. If this happens, we will keep any data that you have already given us

and will use it in the study, but we will not ask you to carry on with any more study activities. The healthcare you receive will not be affected in any way.

What will happen next?

When you have finished reading this, exit this document and click through to the next page from the home screen.

If you are aged 15 years or younger, you will be taken to a web page that will ask if you and your parents would like to help our study and if you both agree, then you can click 'yes'.

If you are aged 16 years or older, you will be taken to a web page that will ask if you would like to help our study, and if you agree then you can click 'yes'.

Once you have confirmed that you would like to take part, you will complete the rest of the consent form with your GP practice's name and town (to identify your GP practice and check it is one of the ones that took part in the original study), and also your date of birth and NHS number in order to find your healthcare records at the GP practice.

We also ask if you would like to be contacted about the results of this research. This is optional.

Will there be the same researchers throughout the study?

As this is a relatively short study, yes we are expecting the same researchers at the start of the study to be involved all the way through.

What will happen to the information that you have about me?

We will only use information that you give us and that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. These people will include researchers from Keele

University, research facilitators helping us from the NIHR (a UK government organisation for health care research) and non-researchers from (or authorised by) Keele University for monitoring and auditing purposes.

We will ask for your post code (but not full address). This is so we can check that people from different areas and backgrounds are included in the study. We will also ask for your date of birth and NHS number so we know your age and can cross check that your date of birth and NHS number matches those already held in SPLaT-19_C database. We will use your date of birth and NHS number to ask for any COVID-19 healthcare records from your GP practice, so it is important we check it is correct first.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. When we need to exchange any of your details between organisations, this will be done using secure encrypted NHS emails using files that will be password protected.

At the end of the study, we will save some of the data for future research. We will make sure no-one can work out who you are from the reports we write. If you would like to know more about how your information is looked after, please see page 6 and 7 for more details.

We want to tell others about the findings of this study so we will present these at conferences and publish them in scientific journals. You will never be identified in these presentations or articles. You will also be able to find a summary of the results on Keele University's website.

Will I be paid for taking part?

There will be no payment for taking part. But we are very grateful for your time.

What might the risks or harms be of taking part?

We do not think there are any significant risks to you in taking part. The information you provide will be managed in the strictest confidence, more details about this can be found on pages 6-8. Please note that if you did tell us anything that was or could cause you or someone else harm (such as someone hurting you), we will have to inform the relevant professionals and not be able to keep that part confidential.

How will taking part help me?

Taking part in this study may not help you but we hope the information you have allowed us to access will help us understand more about long COVID and will go on to help children and young people with Long COVID.

Who is paying for and organising the research?

- The SPLaT_ER study is being led by Dr Glenys Somayajula (Keele University) and other researchers at Keele University. They are working in partnership with Clinical Research Networks in England, GP practices, patients and healthcare professionals in England.
- The study is funded by National Institute of Health and Care Research (NIHR) and by a North Staffordshire Medical Institute Research Award (Twin funded by 'The North Staffordshire Medical Institute' and 'University Hospitals of North Midlands NHS Trust Charity fund')

Who has checked the study?

To protect you, all research is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given approval by Oxford REC (Research Ethics Committee).

Who can I talk to if I have any questions?

If you have any questions, or would like further information about this study, please contact the SPLaT_ER study team at research.splat_er@keele.ac.uk .

What if I need to speak to someone outside of the study team about this study?

If you have any general questions or concerns about taking part in research, you can contact the Patient Advice and Liaison Service (PALS). You can ask your GP surgery, hospital or phone NHS 111 for details of your nearest PALS; further information about PALS is also available at the NHS website:

<https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service>

If you require this document in an alternative format, such as large print or a coloured background, please contact the SPLaT_ER study team at research.splat_er@keele.ac or by telephone on 01782 731273.

Thank you for your time,

From the SPLaT_ER study team

DATA INFORMATION



What will happen to the information collected about me during the research?

Keele University is the sponsor for this study, which is based in the United Kingdom. Keele University will be using information from you in order to undertake this research and will act as the data controller for the data collected during this study. This means that we are responsible for looking after your information and using it properly. Regulatory authorities may look at the data to make sure that we are conducting the study properly.

Keele University will keep some of the information you provide for a minimum of 10 years after the research has finished. Your contact details will only be retained if you provide consent to be contacted about future COVID studies. All data used for analysis will be pseudonymised and will be stored separately from personally identifiable data, in a secure password protected setting. This is normal in research of this nature.

Your identifiable data will be securely stored by Keele University and will not be used beyond the purposes of the study.

How will we use information about you?

We will need to use information about you for this research project.

When your GP practice invited you into the SPLaT-19_C study, your NHS number, age and gender was shared with Keele Clinical Trials Unit at Keele University. If you participate in the SPLaT-ER study, the previously stored NHS number will enable the research team to determine your GP practice, to provide accurate record linkage in this Long COVID study. The NHS numbers of those who do not participate in the study will be deleted at the end of study recruitment. This processing takes place under the lawful basis of a task in the public interest.

Information you provide during the study, such as your name, date of birth, and contact details on your consent form, together with the information we collect from your GP practice will only be used by authorised members of the research team. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at [Research participants - Keele University](#)
- by asking one of the research team
- by sending an email to [Keele University's Data Protection Officer dpo@keele.ac.uk](mailto:dpo@keele.ac.uk)